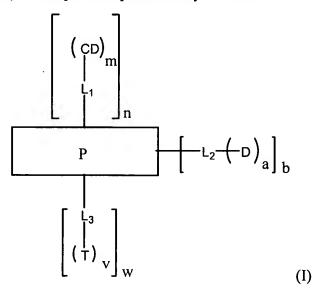
## 18, 2006 Application No. 10/656,838

Docket No.: ITI-P01-008

1. (currently amended) A compound represented by Formula I:



**AMENDMENTS TO THE CLAIMS** 

wherein

P represents a linear polymer backbone chain;

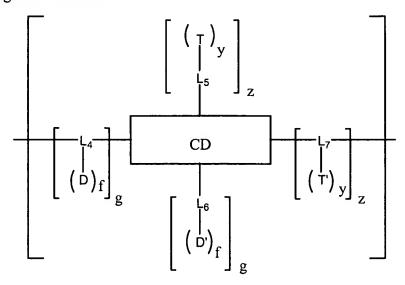
CD represents a cyclodextrin moiety;

L<sub>1</sub>, L<sub>2</sub> and L<sub>3</sub>, independently for each occurrence, may be absent or represent a linker group;
D, independently for each occurrence, represents a therapeutic agent or a prodrug thereof;
T, independently for each occurrence, represents a targeting ligand or precursor thereof;
a, m and v, independently for each occurrence, represent integers in the range of 1 to 10;
n and w, independently for each occurrence, represent an integer in the range of 0 to about
30,000; and

b represents an integer in the range of 1 to about 30,000; and

wherein either P comprises cyclodextrin moieties alternating with linker moieties in the polymer <u>backbone</u> chain or n is at least 1, wherein at least one a plurality of linker moiety moieties in the backbone includes are attached to a therapeutic agent that is releasable under biological conditions.

2. (currently amended) The compound of claim 1, wherein the polymer <u>backbone</u> chain comprises n' units of U, wherein n' represents an integer in the range of 1 to about 30,000; and U is represented by the general formula:



wherein

CD represents a cyclodextrin molecule, or derivative thereof;

L<sub>4</sub>, L<sub>5</sub>, L<sub>6</sub>, and L<sub>7</sub>, independently for each occurrence, may be absent or represent a linker group;

D and D', independently for each occurrence, represent the same or different therapeutic agent or prodrugs thereof;

T and T', independently for each occurrence, represents the same or different targeting ligand or precursor thereof;

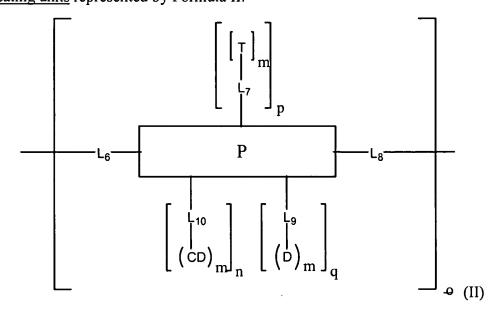
f and y, independently for each occurrence, represent an integer in the range of 1 and 10; and g and z, independently for each occurrence, represent an integer in the range of 0 and 10.

3

3. (currently amended) A linear polymeric compound, with a linear backbone, with up to about 30,000 repeating units represented by Formula II:

Docket No.: ITI-P01-008

Application No. 10/656,838



wherein

P represents a monomer unit of a polymer;

T, independently for each occurrence, represents a targeting ligand or a precursor thereof;

L<sub>6</sub>, L<sub>7</sub>, L<sub>8</sub>, L<sub>9</sub>, and L<sub>10</sub>, independently for each occurrence, may be absent or represent a linker group;

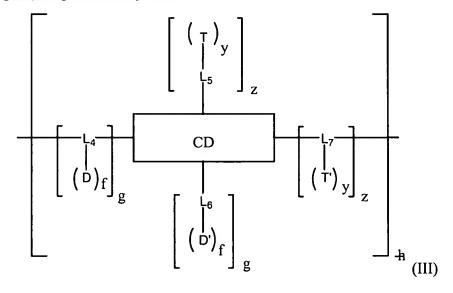
CD, independently for each occurrence, represents a cyclodextrin moiety or a derivative thereof;

D, independently for each occurrence, represents a therapeutic agent or a prodrug form thereof;

m, independently for each occurrence, represents an integer in the range of 1 to 10; <u>and</u> o represents an integer in the range of 1 to about 30,000; and

p, n, and q, independently for each occurrence, represent an integer in the range of 0 to 10, wherein CD and D are each present at least once in the compound.

## 4. (currently amended) A linear polymeric compound, with a linear backbone, with up to about 30,000 repeating units represented by Formula III:



wherein

CD represents a cyclodextrin molecule, or derivative thereof;

L<sub>4</sub>, L<sub>5</sub>, L<sub>6</sub>, and L<sub>7</sub>, independently for each occurrence, may be absent or represent a linker group;

D and D', independently for each occurrence, represent the same or different therapeutic agent or prodrugs thereof, wherein the therapeutic agent is selected from an anti-cancer, anti-fungal, anti-bacterial, anti-mycotic, or anti-viral therapeutic or from anorexics, antiarthritics, antiasthmatic agents, anticonvulsants, antidepressants; antihistamines, anti-inflammatory agents, antinauseants, antineoplastics, antipruritics, antipsychotics, antipyretics, antispasmodics, cardiovascular preparations, antihypertensives, diuretics, vasodilators, central nervous system stimulants, cough and cold preparations, decongestants, diagnostics, hormones, bone growth stimulants and bone resorption inhibitors, immunosuppressives, muscle relaxants, psychostimulants, sedatives, tranquilizers, anti-inflammatory agents, anti-epileptics, anesthetics, hypnotics, sedatives, neuroleptic agents, antidepressants, anxiolytics, anticonvulsant agents, neuron blocking agents, anticholinergic and cholinomimetic agents, antimuscarinic and muscarinic agents, antiadrenergics, antiarrhythmics, and antihypertensive agents;

T and T', independently for each occurrence, represent the same or different targeting ligand or precursor thereof;

f and y, independently for each occurrence, represent an integer in the range of 1 and 10; <u>and</u> h represents an integer in the range of 1 to about 30,000; and g and z, independently for each occurrence, represent an integer in the range of 0 and 10, wherein at least one occurrence of g represents an integer greater than 0.

- 5. (previously presented) The compound of any of claims 1-4, wherein the linker group or linker moiety represents a hydrocarbylene group wherein one or more methylene groups is optionally replaced by a group Y (provided that none of the Y groups are adjacent to each other), wherein each Y, independently for each occurrence, is selected from, substituted or unsubstituted aryl, heteroaryl, cycloalkyl, heterocycloalkyl, or -O-, C(=X) (wherein X is NR<sub>1</sub>, O or S), -OC(O)-, -C(=O)O, -NR<sub>1</sub>-, -NR<sub>1</sub>CO-, -C(O)NR<sub>1</sub>-, -S(O)<sub>n</sub>- (wherein n is 0, 1, or 2), -OC(O)-NR<sub>1</sub>, -NR<sub>1</sub>-C(O)-NR<sub>1</sub>-, -NR<sub>1</sub>-C(NR<sub>1</sub>)-NR<sub>1</sub>-, and -B(OR<sub>1</sub>)-; and R<sub>1</sub>, independently for each occurrence, represents H or a lower alkyl.
- 6. (previously presented) The compound of any of claims 1-4, wherein the linker group or linker moiety represents an amino acid or peptide, or derivative thereof.
- 7. (original) The compound of any of claims 1-4, wherein said therapeutic agent is a small molecule, a peptide, a protein or a polymer that has therapeutic activity.
- 8. (previously presented) The compound of any of claims 1-4, wherein the therapeutic agent is hydrophobic and has a  $\log P > 0.4$ .
- 9. (original) The compound of any of claims 1-4, wherein the therapeutic agent has low aqueous solubility.

10. (previously presented) The compound of any of claims 1-4, wherein the therapeutic agent or targeting ligand is covalently bonded to the linker group or linker moiety via a biohydrolyzable bond.

- 11. (original) The compound of claim 10, wherein the biohydrolyzable bond is selected from an ester, amide, carbonate, or a carbamate.
- 12. (previously presented) The compound of any of claims 1-4, wherein the therapeutic agent is selected from an anti-cancer, anti-fungal, anti-bacterial, anti-mycotic, or anti-viral therapeutic.
- 13. (original) The compound of any of claims 1-4, wherein the therapeutic agent is a receptor agonist.
- 14. (original) The compound of any of claims 1-4, wherein the therapeutic agent is a receptor antagonist.
- 15. (original) The compound of any of claims 1-4, wherein the compound is biodegradable or bioerodable.
- 16. (original) The compound of any of claims 1-4, wherein the compound has a number average  $(M_n)$  molecular weight between 1,000 to 500,000 amu.
- 17. (original) The compound of any of claims 1-4, wherein the polymer has a number average  $(M_n)$  molecular weight between 5,000 to 200,000 amu.
- 18. (original) The compound of any of claims 1-4, wherein the polymer has a number average  $(M_n)$  molecular weight between 10,000 to 100,000 amu.
- 19. (original) A pharmaceutical preparation comprising a pharmaceutical excipient and a compound of any of claims 1-4, or a pharmaceutically acceptable ester, salt, or hydrate thereof.

20. (cancelled)

21. (withdrawn) A method for treating an animal comprising administering a therapeutically effective amount of one or more of the compounds of any of claims 1-4.

Docket No.: ITI-P01-008

Application No. 10/656,838

- 22. (withdrawn) A method for conducting a pharmaceutical business, comprising:
- a. manufacturing a formulation or kit including a pharmaceutical composition of any of the compounds of claim 1, 2, 3, or 4; and
- b. marketing to healthcare providers the benefits of using the formulation or kit in the treatment of a disease or disorder.
- 23. (withdrawn) A method for conducting a pharmaceutical business, comprising:
- a. providing a distribution network for selling a pharmaceutical composition of any of the compounds of claim 1, 2, 3, or 4; and
- b. providing instruction material to patients or physicians for using the preparation in the treatment of a disease or disorder.
- 24. (withdrawn) A method for conducting a pharmaceutical business, comprising:
- a. determining an appropriate formulation and dosage of a pharmaceutical composition of any of the compounds of claim 1, 2, 3, or 4;
- b. conducting therapeutic profiling of formulations identified in step (a), for efficacy and toxicity in animals; and
- c. providing a distribution network for selling a preparation or preparations identified in step (b) as having an acceptable therapeutic profile.
- 25. (withdrawn) The method of claim 24, including an additional step of providing a sales group for marketing the preparation to healthcare providers.
- 26. (withdrawn) A method for conducting a pharmaceutical business, comprising:

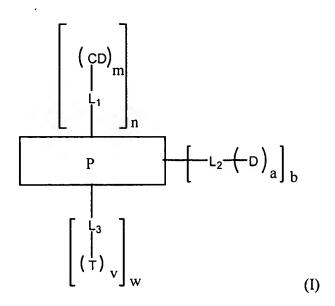
- a. determining an appropriate formulation and dosage of a pharmaceutical composition of any of the compounds of claim 1, 2, 3, or 4; and
- b. licensing, to a third party, the rights for further development and sale of the formulation.
- 27. (cancelled)
- 28. (withdrawn) A modified cyclodextrin ring, wherein exactly two hydroxyl moieties are replaced by a nitrogen or sulfur atom of an amino acid.
- 29. (withdrawn) A modified cyclodextrin ring of claim 28, wherein the amino acid is an alphaamino acid.
- 30. (withdrawn) A modified cyclodextrin ring of claim 29, wherein the amino acid is cysteine, tryptophan, glutamic acid, aspartic acid, lysine, arginine, histidine, or arginine.
- 31. (withdrawn) A modified cyclodextrin ring of claim 28, wherein the amino acid is included in an oligopeptide comprising 2 to 50 amino acid residues.
- 32. (withdrawn) A modified cyclodextrin ring of claim 31, wherein the oligopeptide comprises 2-30 amino acid residues.
- 33. (withdrawn) A modified cyclodextrin ring of claim 31, wherein the oligopeptide comprises 2-15 amino acid residues.
- 34. (previously presented) A linear, water-soluble, cyclodextrin-containing polymer, comprising cyclodextrin moieties alternating with linker moieties in the polymer chain, wherein a plurality of bioactive moieties are covalently attached to the polymer through attachments to the linker moieties that are cleaved under biological conditions to release the bioactive moieties, wherein administration of the polymer to a patient results in release of the bioactive moieties.

35. (previously presented) The compound of any of claims 1-4, wherein the therapeutic agent is selected from anorexics, antiarthritics, antiasthmatic agents, anticonvulsants, antidepressants; antihistamines, anti-inflammatory agents, antinauseants, antineoplastics, antipruritics, antipsychotics, antipyretics, antispasmodics, cardiovascular preparations, antihypertensives, diuretics, vasodilators, central nervous system stimulants, cough and cold preparations, decongestants, diagnostics, hormones, bone growth stimulants and bone resorption inhibitors, immunosuppressives, muscle relaxants, psychostimulants, sedatives, tranquilizers, anti-inflammatory agents, anti-epileptics, anesthetics, hypnotics, sedatives, neuroleptic agents, antidepressants, anxiolytics, anticonvulsant agents, neuron blocking agents, anticholinergic and cholinomimetic agents, antimuscarinic and muscarinic agents, antiadrenergics, antiarrhythmics, and antihypertensive agents.

Docket No.: ITI-P01-008

Application No. 10/656,838

- 36. (previously presented) The compound of any of claims 1-4, wherein the therapeutic agent or prodrug thereof makes up at least 5% by weight of the compound.
- 37. (previously presented) The compound of any of claims 1-4, wherein the therapeutic agent or prodrug thereof makes up at least 20% by weight of the compound.
- 38. (previously presented) The compound of any of claims 1-4, wherein the compound is water soluble.
- 39. (currently amended) A compound represented by Formula I:



wherein

P represents a linear polymer backbone chain;

CD represents a cyclodextrin moiety;

L<sub>1</sub>, L<sub>2</sub> and L<sub>3</sub>, independently for each occurrence, may be absent or represent a linker group;

D, independently for each occurrence, represents a therapeutic agent or a prodrug thereof, wherein the therapeutic agent is selected from an anti-cancer, anti-fungal, anti-bacterial, anti-mycotic, or anti-viral therapeutic or from anorexics, antiarthritics, antiasthmatic agents, anticonvulsants, antidepressants; antihistamines, anti-inflammatory agents, antinauseants, antineoplastics, antipruritics, antipsychotics, antipyretics, antispasmodics, cardiovascular preparations, antihypertensives, diuretics, vasodilators, central nervous system stimulants, cough and cold preparations, decongestants, diagnostics, hormones, bone growth stimulants and bone resorption inhibitors, immunosuppressives, muscle relaxants, psychostimulants, sedatives, tranquilizers, anti-inflammatory agents, anti-epileptics, anesthetics, hypnotics, sedatives, neuroleptic agents, antidepressants, anxiolytics, anticonvulsant agents, neuron blocking agents, anticholinergic and cholinomimetic agents, antimuscarinic and muscarinic agents, antiadrenergics, antiarrhythmics, and antihypertensive agents;

T, independently for each occurrence, represents a targeting ligand or precursor thereof; a, m and v, independently for each occurrence, represent integers in the range of 1 to 10;

n and w, independently for each occurrence, represent an integer in the range of 0 to about 30,000; and

b represents an integer in the range of 1 to about 30,000; and wherein either P comprises cyclodextrin moieties or n is at least 1.

- 40. (new) The compound of any one of claims 1 or 39, wherein at least one of the cyclodextrin moieties of P is oxidized.
- 41. (new) The compound of claim 40, wherein a plurality of the cyclodextrin moieties of P are oxidized.
- 42. (new) The compound of any one of claims 2 or 4, wherein at least one occurrence of CD is oxidized.
- 43. (new) The compound of claim 42, wherein a plurality of occurrences of CD are oxidized.

12